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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,341

04/14/2004

Gary W. Guenst

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

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MAIL DATE

DELIVERY MODE

12/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,341	Applicant(s) GUENST, GARY W.	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-20, and 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal brief filed on 15 September 2008, PROSECUTION IS
HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the
following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply
under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed
by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and
appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth
in 37 CFR 41.20 have been increased since they were previously paid, then appellant
must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by
signing below:

/s/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-7, 9-13, 32-34, 36-38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Duhaylongsod et al. (U.S. Patent No. 6,241,741 B1)**.

Duhaylongsod discloses a method of joining a blood conduit to a blood vessel (see entire document) comprising the steps of making an incision (18) in the blood vessel wall (14), inserting a tubular member (80) into a conduit (26,12), advancing the tubular member through the incision located on a proximal end thereof (for example, see Figure 7), fixedly joining the conduit to the vessel wall (balloon, or weakened wall region, is inflated, or expanded radially outward, expanding the end portion of the conduit to engage the wall and also discloses may utilize biological glue), and after fixedly joining the conduit to the vessel withdrawing the tubular member through the conduit (for example, see column 7, lines 17-48).

Duhaylongsod discloses another embodiment in which oxygenated liquid flow (blood) is provided through a tubular member and into the blood vessel while fixedly joining a conduit (via holes 98 within tubular member 90; for example, see Figures 18-20 and column 8, lines 22-25). It is well within the general knowledge of one having

ordinary skill in the art to combine prior art elements to yield predictable results.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to fixedly join the conduit of the first embodiment while providing an oxygenated liquid flow through the tubular member and into the blood vessel as shown in the second embodiment. Doing so would enable blood to continue to be supplied downstream the anastomosis site (for example, see column 8, lines 22-24).

With respect to claims 2 and 33, Duhaylongsod discloses inserting a tubular member into a conduit and advancing a tubular member through a vessel (see rejection above), wherein the inserting is performed after the advancing. Applicant has not disclosed that performing the inserting before advancing provides an advantage, is used for a particular purpose, or solves a stated problem over inserting after advancing. Furthermore, Applicant discloses that the inserting may be performed either before or after advancing. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the inserting before the advancing, since the reversal of these steps involves only routine skill in the art.

With respect to claims 5, 6, 36, and 37, Duhaylongsod discloses the blood vessel may be a coronary artery. Applicant has not disclose that utilizing a saphenous vein or internal mammary artery as the conduit provides an advantage, is used for a particular purpose, or solves a stated problem over utilizing other veins, arteries, and synthetic vascular grafts. Furthermore, both Applicant and Duhaylongsod disclose that in addition to a thoracic artery, other vessels, arteries, or synthetic vascular grafts may be used.

Therefore, it would have been obvious to modify the conduit of Duhaylongsod to obtain the invention as specified in claims 5, 6, 36, and 37.

With respect to claims 10-12, 40, and 41 Duhaylongsod discloses the oxygenated fluid includes blood. Applicant has not disclosed that utilizing blood supplied from the femoral artery or aorta, or utilizing a non-blood oxygenated carrying substance provides an advantage, is used for a particular purpose, or solves a stated problem over utilizing simply blood (from any location). Furthermore, Applicant discloses that any suitable oxygenated fluid can be used to provide the needed oxygen to the blood vessel undergoing the anastomosis. Therefore, it would have been obvious to modify the liquid of Duhaylongsod to obtain the invention as specified in claims 10-12, 40, and 41.

Regarding claim 32, Duhaylongsod's graft connection position has been considered to be "near the blood vessel proximal end" of the blood vessel. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to position the graft connection to or near the blood vessel proximal end, since the applicant has not disclosed that positioning the graft connection at or near the blood vessel proximal end provides an advantage is used for a particular purpose, or solves a stated problem and it appears the invention would perform equally well at the position disclosed by Duhaylongsod.

Claims 4 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Duhaylongsod et al. in view of Stanish (U.S. Patent No. 6,585,762 B1)**.

Duhaylongsod discloses a method as described above, however, fails to disclose fixedly

joining includes suturing the conduit to the blood vessel. Stanish discloses a method of joining a blood conduit to a blood vessel wall (see entire document). Stanish teaches suturing the conduit to the blood vessel wall in order to advantageously secure the conduit to the vessel (for example, see column 7, lines 37-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to suture the conduit to the blood vessel in the method of Duhaylongsod as taught by Stanish. Doing so would ensure the conduit and vessel are secured together.

Claims 8, 14, 16-20, 39, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Duhaylongsod et al. in view of Amor et al. (U.S. Patent No. 6,059,809)**. Duhaylongsod discloses a method as described above, however, fails to disclose inserting a stiffening member within the tubular member, and wherein the expanding includes forcing the oxygenated fluid under pressure through the tubular member to expand the weakened distal region and into the blood vessel. Amor discloses a method (see entire document) comprising the steps of inserting a tubular member (4) through a conduit (8) and into a vessel. Amor teaches inserting a stiffening member (6) within the tubular member (4) and providing fluid through the tubular member, which inflates the weakened distal region (12), into the vessel at a pressure higher than the patient's blood pressure through ports (25) distinct from the proximal end (for example, see Figure 3 and column 4, lines 41-49) in order to flush the area of debris (for example, see column 3, lines 17-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the

method steps of Amor in the method of Duhaylongsod. Doing so would provide a means of flushing the anastomosis site during the procedure, thus deviating debris to other places of the body where they can provoke no harm.

With further respect to claims 8, 16, and 39, it would have been obvious to one of ordinary skill in the art at the time the invention was made as a matter of design choice to provide the device of Duhaylongsod in view of Amor with a flow restrictor and a bulb for providing the fluid pressure, since such mechanisms are well known in the art (for example, see Blum's patent 4,230,119; restrictor 20 and bulb 13).

Response to Arguments

Applicant's arguments filed in the appeal brief dated 15 September have been fully considered but they are not persuasive. It is noted that the new ground of rejection above combines prior art elements instead of substituting prior art elements as described in the rejection dated 05 February 2008.

The applicant argues that the two separate embodiments of Duhaylongsod et al. are not properly combinable because they include different approaches and are used for different reasons. The applicant states that the physical approach of the catheter shown in Figures 5-8 is from outside the vessel and the reason for using it is to expand the fastener to fit against the inner wall of the vessel, wherein blood flow in the vessel is not occluded by the catheter or fastener. The applicant further states that the physical approach of the catheter shown in Figures 18-20 is intravascular and the reason for using it is to supply blood to the vessel downstream from the anastomosis site because the balloon (92) on the catheter completely occludes blood flow through the vessel. The

applicant argues that since there is no complete occlusion in the embodiment shown in Figures 5-8, blood supply is already provided and thus there is no reason to provide any additional supply. However, Figure 8 clearly shows that there comes a point when the balloon and fastener do occlude blood flow. Therefore, it is the examiner's position that there is reason to combine the embodiments and provide blood flow through the tubular member. Doing so would enable blood to continue to be supplied downstream the anastomosis site when blood flow provided by the vessel is occluded. The applicant further argues that since the embodiments include different approaches, it would not be possible for the balloons on the catheter shown in Figures 18-20 to be located upstream from the anastomosis site for the purpose of occlusion of the vessel at the anastomosis site, while the openings would be downstream to supply blood downstream from the occlusion. However, the method steps of Figures 5-8 are not being modified with the step of providing the balloons upstream from the anastomosis site. The method steps are simply being modified with the step of providing an oxygenated liquid flow through the tubular member and into the vessel. The applicant has not provided any reasons as to why the step of providing an oxygenated liquid flow through the tubular member and into the vessel would not work in the embodiment shown in Figures 5-8. Therefore, it is the examiner's position that the method step is combinable with the embodiment shown in Figures 5-8.

Regarding the applicant's argument that Duhaylongsod fails to disclose a graft connection to or near an end of any blood vessel, claims in a pending application should be given their broadest reasonable interpretation. Duhaylongsod's graft connection

position, giving the broadest reasonable interpretation, has been considered to be "near the blood vessel proximal end" of the blood vessel. In the alternative, such a modification is considered an obvious variant (see rejection above).

Regarding the applicant's arguments that Duhaylongsod teaches away from using sutures to join a conduit to a blood vessel since they teach the use of expandable fasteners instead, preferred or exemplary embodiments do not indicate a "teaching away" from other embodiments well known in the art. It would have been obvious to one having ordinary skill in the art at the time to perform the step of suturing in Duhaylongsod's method in order to enhance attachment, thus minimizing risk of inadvertent detachment.

Regarding the applicant's argument that there is no need to provide Duhaylongsod's method with the step of flushing since there is no blockage, it is well known that creating incisions and inserting conduits and/or other devices into blood vessels may cause debris. Therefore, fluid provided does not have to be used solely for the purposes of removing the blockage, but may be used to flush unwanted debris in the vessel surrounding the bypassed area, thus further facilitating the procedure.

Conclusion

Applicant's amendment dated 02 July 2007 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
November 18, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773